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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/554,844 | 09/19/2000 | Volker Zimmer | RDID0044US | 9010 |
| 7590 06/03/2004 | | | | |
| Jill L Woodburn The Law Office of Jill L. Woodburn LLC 6633 Old Stonehouse Drive Newburgh, IN 47630 | | | EXAMINER PADMANABHAN, KARTIC | |
| | | | ART UNIT 1641 | PAPER NUMBER |

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 09/554,844 | Applicant(s) ZIMMER ET AL. | |
| | Examiner Kartic Padmanabhan | Art Unit 1641 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,5,7-10,13 and 15-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3,5,7-10,13 and 15-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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4. Claims 2-3, 7-10, 13, 15-27, and 29-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamada (US Pat. 5,399,316) in view of Hodges et al. (US Pat. 5,942,102) and Zimmer et al. (US Pat. 5,814,522).

Yamada discloses a device (10) for conducting an immunological assay (see ABSTRACT; FIGURE). The device (10) comprises a carrier (17), detection element, cover (11) with a surface that cooperates with a surface of the carrier (17) to form a capillary-active channel (14), second cover (24), and intermediate layer (12,13) positioned between the second cover (24) and carrier (11) (see FIGURE). Since the instant specification (page 10) discloses that the detection element (2) may be a reagent-impregnated membrane, the detection element may be considered the specific affinity material placed in the reaction region (21) (see COL. 6, lines 55 and 56). The specific affinity material may be chemically or physically bound to at least one surface of the cover (11), intermediate layers (12, 13), or carrier (17) (see COL. 6, lines 56-59). Alternatively, an insoluble material to which a specific affinity material is bound may be placed in the reaction region (21) so as not to interfere with the flow of the solution inside the capillary-active channel (14) (see COL. 6, lines 59-63). In this case, one would expect that the insoluble material would have opposite first and second ends with the first end being positioned adjacent to the carrier. Since the specific affinity material is placed in the channel (14), one would also expect that the cover (11) would also cooperate with a surface of the detection element to form the channel (14). After sufficient time has passed for a reaction to occur, a detection unit of a measuring apparatus, such as a photoelectron multiplier is located above the carrier (17), which covers the reaction region (21), and the amount of light emitted from the reaction region (21) is measured (see COL. 7, line 67-COL. 8, line 44). In the event one would argue that the specific

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affinity material is not an element distinct from the cover as shown in the drawings of the instant application, it would have been obvious to one having ordinary skill in the art at the time the invention was made to separate the specific affinity material from the cover since it provides flexibility in testing different assays by allowing placement of different specific affinity material to be placed into the reaction region especially when the device is disclosed as reusable (see COL. 7, lines 26-41). Furthermore, it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art (*Nerwin v. Erlichman*, 168 USPQ 177,179).

The channel (14) has a sample application opening (22) defined by at least one edge (see FIGURE). The channel (14) extends at least from the opening to the second end of the detection element since excess liquid is absorbed by member (28), an ancillary element that may be attached to the end of the channel (14) or second end of the reaction region (21) (see FIGURE). The at least one notch (15,16) in the form of a partial groove is positioned at the at least one edge of the sample application opening (22) of the channel (14) such that one side of the edge of the sample application opening (22) is at least partially interrupted by the at least one notch (15,16), and the surface facing opposite to the at least one notch (15,16) facing the channel (14) is exposed. A liquid sample is contacted with the edge of the sample application opening (22) adjacent to the notch (15,16) such that the liquid sample is immediately transported by capillary forces into the channel (14) (see ABSTRACT; FIGURE; SUMMARY OF THE INVENTION; COL. 5, lines 13-31; COL. 6, lines 64-68; COL. 7, lines 1-68., COL. 8, lines 1-9 and 14-36). However, the reference does not teach a notch such that at least one edge of the sample

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application opening is at least partially discontinuous and a surface opposite the notch is exposed.

Hodges et al. teach an electrochemical detection method and device, wherein a notch is provided in the channel to allow sample to be admitted or drawn in by wicking or capillary action and to allow air to escape. However, the reference does not teach a vent, filtration means, or foil.

Zimmer et al. teach a multilayer analytical element and method for the determination of analyte in a liquid; wherein said element comprises an application zone and detection zone side by side on a stacked complex composed of fleece and a porous membrane, wherein said fleece and porous membrane are in fluid contact via a contact area which permits passage of fluid there through, a portion of said porous membrane being in the detection zone and having a detection reagent which forms a signal upon interaction with analyte. Sample may be applied directly to the sample application zone, but the use of a capillary channel is also compatible with the device of the reference. One possible embodiment of the analytical element is the location of the fleece and membrane on a support foil which has a hole in the area of the test zone containing reagent. A covering foil is attached with a spacer on the fleece side in such a way that there is a capillary gap in the sample application zone. There may be a vent if the channel is only open at the inlet side. The porosity of the membrane acts to filter out certain particles. Analyte presence can be determined visually or by an instrument.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the notch in the device of Yamada with the notch of Hodges et al. because it allows for a small amount of sample to be drawn into the channel via capillary action,

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while also allowing air to escape from the channel. In addition, it would have been obvious to use a vent and filtration means as in Zimmer et al. with the modified device and method of Yamada and Hodges et al. because Zimmer et al. teaches that a vent is necessary when the channel is only open at the one end, and filtration means allows for the removal of various substances that may block the channel or interfere with the operation of the device in some other way. Further, it would have been obvious to use foil as taught by Zimmer et al. because foil provides a good supporting material, while being inert so as not to interfere with the assay in any meaningful way.

5. Claims 5 and 28 rejected under 35 U.S.C. 103(a) as being unpatentable over Yamada (US Pat. 5,399,316) in view of Hodges et al. (US Pat. 5,942,102) and Zimmer et al. (US Pat. 5,814,522), as applied to claims 2-3, 7-10, 13, 15-27, and 29-40 above, and further in view of Heller et al. (US Pat. 6,238,624).

Yamada, Hodges et al., and Zimmer et al. teach a modified device and method for conducting an assay, as previously discussed. However, the references do not teach using oxidized aluminum for hydrophilization.

Heller et al. teach forming lawn type permeation layers by attaching bifunctional linear or polymeric hydrophilic molecules to a metal surface in fabricating a microelectronic device to carry out and control multi-step and multiplex molecular biological reactions in microscopic format, which are significant in clinical diagnostics (see ABSTRACT, COL. 16, lines 55-64). The preferred procedure for producing a lawn type structure involves derivatization of the metal microelectrode surface using aminopropyltriethoxy silane (APS) (see COL. 17, lines 13-15). APS provides a combined permeation and attachment layer with primary amine groups for

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covalent coupling of binding entities, especially oligonucleotides (see COL. 17, lines 17- 19, 38, and 39). APS provides a high level of functionalization in terms of surface binding sites on slightly oxidized aluminum (see COL. 17, lines 20-22).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to use oxidized aluminum for hydrophilization as in Heller et al. in the modified device and method of Yamada, Hodges et al., and Zimmer et al. to provide a high level of surface binding sites to bind targeted entities in sample liquid diagnostics.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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7. Claims 2-3, 5, 7-10, 13, and 15-40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,592,815. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite analytical test elements and methods of detection comprising similar elements and steps, and one of ordinary skill in the art would recognize that the two sets of claims read on each other.

Response to Arguments

8. Applicant's arguments with respect to claims 2, 3, 5, 7-10, 13, and 15-40 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Claims 2, 3, 5, 7-10, 13, and 15-40 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 571-272-0825. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kartic Padmanabhan
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Art Unit 1641



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05/01/04